HIGH RISK ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES RESEARCH

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National Institute of Arthritis and Musculoskeletal and Skin Diseases

Letters of Intent Receipt Date: January 15, 2002
Application Receipt Date: February 14, 2002

THIS RFA USES "MODULAR GRANT" AND "JUST-IN-TIME" CONCEPTS. MODULAR INSTRUCTIONS MUST BE USED FOR RESEARCH GRANT APPLICATIONS REQUESTING LESS THAN $250,000 PER YEAR IN ALL YEARS. MODULAR BUDGET INSTRUCTIONS ARE PROVIDED IN SECTION C OF THE PHS 398 (REVISION 5/2001) AVAILABLE AT http://grants.nih.gov/grants/funding/phs398/phs398.html.

PURPOSE

The purpose of this initiative is to broaden the base of inquiry in fundamental biomedical, bio-behavioral, and biomedical technology research by encouraging applications for research projects that involve an especially high degree of innovation and novelty and, therefore, require a preliminary test of feasibility. The research projects proposed under this Request for Applications (RFA) may involve substantial experimental risks such that their potential for highly significant outcomes may be difficult to judge by the standard criteria used in evaluating investigator initiated (R01) proposals. Preliminary data are not required. The work proposed may not overlap with the aims of currently supported projects in which the Principal Investigator has participated during the last five years. Proposed projects must support the mission of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS).

Two kinds of experienced investigators are sought. First, established investigators in arthritis or musculoskeletal or skin diseases are encouraged to present a proposal for testing the feasibility of a novel idea, resource or technology. The project should represent a clear and distinct departure from the investigator's ongoing research. Second, established investigators with no previous work in arthritis or musculoskeletal or skin diseases are encouraged to apply their expertise to research that is relevant to arthritis or musculoskeletal or skin diseases.

HEALTHY PEOPLE 2010

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This RFA, “High Risk Arthritis and Musculoskeletal and Skin Diseases Research,” is related to the priority area of chronic diseases. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople/.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and nonprofit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators. Participation in the program by investigators at minority institutions is strongly encouraged.

The proposed work must be new and not overlap with projects in which the Principal Investigator has participated during the last five years. Projects that could reasonably be considered a logical and immediate extension of current work are not within the scope of this RFA. (Information on past projects is to be provided as part of the Principal Investigator's Biographical Sketch, as described below under Application Procedures.) Applications will be programmatically reviewed by NIAMS staff for eligibility before they are formally accepted. Applications that do not meet the above criteria will be returned to the Principal Investigator prior to review. Investigators who have questions about eligibility should contact one of the program officials listed under INQUIRIES.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) exploratory/developmental research grant, R21, award mechanism. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Applicants may request up to $50,000 (direct costs) per year for up to two years. These awards are not renewable. If desired, the specific aims of the R21 project may be incorporated into a research project grant application (R01) submitted prior to the termination of the R21 award. This RFA is a one-time solicitation.

FUNDS AVAILABLE

It is anticipated that for FY 2002, approximately $1,200,000 total costs will be available for the first year of support for this initiative. Award of grants is contingent upon the receipt of such funds for this purpose. It is anticipated that up to 20 new grants will be awarded under this program. The specific number to be funded will depend on the merit and scope of the applications received and on the availability of funds. Direct costs are limited to $50,000 and will be awarded in modules of $25,000, less any overlap or other necessary administrative adjustments. Facilities and Administrative costs will be awarded based on the negotiated rates. Applicants may request up to two years of support.

RESEARCH OBJECTIVES

The NIAMS seeks to broaden the base of inquiry in fundamental biomedical, bio-behavioral, and biomedical technology research by encouraging research projects that involve a high degree of innovation and novelty. Because innovative projects may require a preliminary test of feasibility, this initiative will provide short-term support for such preliminary work. Each research plan should begin with a short paragraph describing how the proposed project represents a high degree of innovation and novelty that does not overlap with the applicant's recently funded research. The projects must support the NIAMS mission as detailed in the NIAMS World Wide Web home page, which can be found at http://www.nih.gov/niams/about/ep1.htm. In brief, the NIAMS supports research in: a) rheumatic diseases; b) cartilage biology and diseases; c) bone biology and diseases (e.g., osteogenesis imperfecta, Paget's disease); d) skin biology and skin diseases; e) autoimmune diseases (e.g., lupus, rheumatoid arthritis); f) connective tissue diseases; g) musculoskeletal diseases (e.g., osteoarthritis, osteoporosis) h) musculoskeletal imaging; i) injuries and disorders of the musculoskeletal system; j) muscle biology and diseases (e.g., muscular dystrophy); k) exercise physiology and musculoskeletal fitness; l) sports injuries; m) occupational diseases and injuries; and n) orthopaedic and bioengineering topics.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the UPDATED "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," published in the NIH Guide for Grants and Contracts on August 2, 2000 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html); a complete copy of the updated Guidelines is available at: http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm and additional information can be found at:http://grants.nih.gov/grants/funding/women_min/women_min.htm. The revisions relate to NIH defined Phase III clinical trials and require: a) all applications or proposals and/or protocols to provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) all investigators to report accrual, and to conduct and report analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research conducted or supported by the NIH unless there are scientific or ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998. http://grants.nih.gov/grants/funding/children/children.htm

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the Inclusion of Children as Participants in Research Involving Human Subjects that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: http://grants.nih.gov/grants/guide/notice-files/not98-024.html.

Investigators also may obtain copies of these policies from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000, at the following web site: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

URLS IN NIH GRANT APPLICATIONS OR APPENDICES

All applications and proposals for NIH funding must be self-contained within specific page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URL) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at: http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this RFA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

LETTER OF INTENT

Prospective applicants are asked to submit, by January 15, 2002, a letter of intent that includes a descriptive title of the proposed research; the name, address, and telephone number of the Principal Investigator; the identities of other key personnel and participating institutions; and the number and title of this RFA. Although a letter of intent is not required, is not binding, does not commit the sender to submit an application, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review. The letter of intent is to be sent (e-mail, fax or post) to Dr. Tommy Broadwater at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The PHS 398 research grant application instructions and forms (rev. 5/2001) available at http://grants.nih.gov/grants/funding/phs398/phs398.html must be used in applying for these grants. This version of the PHS 398 is available in an interactive, searchable format. For further assistance contact GrantsInfo, Telephone 301/435-0714, Email: GrantsInfo@nih.gov.

SPECIFIC INSTRUCTIONS FOR MODULAR GRANT APPLICATIONS

The modular grant concept establishes specific modules in which direct costs may be requested as well as a maximum level for requested budgets. Only limited budgetary information is required under this approach. The just-in-time concept allows applicants to submit certain information only when there is a possibility for an award. It is anticipated that these changes will reduce the administrative burden for the applicants, reviewers and NIH staff. The research grant application form PHS 398 (rev. 5/2001) at http://grants.nih.gov/grants/funding/phs398/phs398.html is to be used in applying for these grants, with modular budget instructions provided in Section C of the application instructions. For further assistance contact GrantsInfo, Telephone 301/435-0714, Email: GrantsInfo@nih.gov.

The Background and Significance Section of application should specifically state how the project represents a new direction for the work performed at the PI's laboratory. This should include a brief section (one page or less) entitled "Qualifications for High Risk" in which the PI specifically addresses the following concerns:

Innovation & Novelty: Does the proposed project represent a high degree of innovation and novelty?

Departure from current work: Does the proposed project specifically overlap with work from the PI during the last five years?

How does the proposed work represent a significant departure from the PI's current line of work?

High risk: Explain how the high gain potential of the project, if successful, offsets the high risk of failure.

A Preliminary Data section is not required. If included in R21 applications, it should not exceed one page. The research plan (a-d) is limited to 10 pages. Applications that exceed the page limit will be returned without review. An appendix may be included in the application; however, the appendix is not to be used to circumvent the page limit of the research plan.

The RFA label available in the PHS 398 (rev. 5/2001) application form must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at: http://grants.nih.gov/grants/funding/phs398/label-bk.pdf.

Submit a signed, typewritten original of the application and three signed photocopies, in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC-7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application must be sent to:

Tommy L. Broadwater, Ph.D.
Scientific Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS-25U - MSC 6500
Bethesda, MD 20892-6500
In order not to delay review, it is important that applicants comply with this request.

Applications must be received by February 14, 2002. If an application is received after that date, it will be returned to the applicant without review. A Principal Investigator may submit only one R21 grant application.

The Center for Scientific Review (CSR) will not accept any application in response to the RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as

one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an Introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by CSR and responsiveness by NIAMS. Incomplete and/or non-responsive applications will be returned to the applicant without further consideration. Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NIAMS in accordance with the review criteria stated below. As part of the initial merit review, all applications will receive a written critique; however, only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed, assigned a priority score, and receive a second level review by the NIAMS Advisory Council.

REVIEW CRITERIA

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. For this initiative, the proposed project must have the potential for developing ground-breaking technology or methodology that may lead to significant expansion of biomedical research horizons, precipitate a paradigm shift in research, or lead to substantial improvements in human health. In the written review, comments on the following aspects of the application will be made in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in the assignment of the overall score.

(1) Significance. Does the proposed study clearly not overlap with recently funded research? Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

(2) Approach. Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the investigator acknowledge potential problem areas and consider alternative tactics?

(3) Innovation. Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or seek to develop new

methodologies or technologies? Does the proposed project specifically overlap with work from the PI during the last five years? Does the proposed work represent a significant departure from the PI's current line of work? Does the high gain potential of the project, if successful, offsets the high risk of failure?

(4) Investigator. Is the investigator appropriately trained and well suited to carry out this work? Is the proposed work appropriate to the experience level of the principal investigator and other researchers (if any)?

(5) Environment. Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

In addition to the above criteria, in accordance with NIH policy, all applications will also be reviewed with respect to the following:

o The adequacy of plans to include both genders, minorities and their subgroups, and children as appropriate for the scientific goals of the research and in conformance with the NIH Guidelines for the Inclusion of Women and Minorities as Subjects in Clinical Research and Inclusion of Children as Participants in Research Involving Human Subjects. Plans and for recruitment and retention of subjects will also be evaluated.

o The adequacy of the proposed protection for humans, animals, or the environment, to the extent they may be adversely affected by the project proposed in the application.

o The appropriateness of staffing based on the requested percent effort and the personnel budget. The direct costs budget request will be reviewed for consistency with the proposed methods and specific aims. Any budgetary adjustments recommended by the reviewers will be in $25,000 modules. The duration of support will be reviewed to determine if it is appropriate to ensure successful completion of the requested scope of the project.

o The potential for ground-breaking, precedent setting significance of the proposed research with particular emphasis on novel and innovative approaches that clearly require additional preliminary data for their value to be established.

SCHEDULE

Letter of Intent Date: January 15, 2002
Application Receipt Date: February 14, 2002
Council Review: September 26, 2002
Earliest Anticipated Start Date: September 30, 2002

AWARD CRITERIA

The following will be considered in making funding decisions:

o Scientific merit of the proposed project as determined by peer review
o Programmatic importance of the area to NIAMS research
o Availability of funds

INQUIRIES

Inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to the most appropriate person listed on the web site (http://www.niams.nih.gov/rtac/prog_staff/director.htm) according to scientific area or for general inquiries about this RFA contact:

Dr. Gayle E. Lester
45 Center Drive, Room 5AS-43C
Bethesda, MD 20892-6500
Telephone: (301) 594-5055
FAX: (301) 480-4543
Email: gl83g@nih.gov

Direct inquiries regarding review matters to:

Dr. Tommy L. Broadwater
Scientific Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS-25U - MSC 6500

Bethesda, MD 20892-6500
Telephone: (301) 594-4952
FAX: (301) 480-4543
Email: broadwat@mail.nih.gov

Direct inquiries regarding fiscal matters to:

Melinda B. Nelson
Grants Management Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS-49F, MSC 6500
Bethesda, MD 20892-6500
Telephone: (301) 594-3535
FAX: (301) 480-5450
Email: nelsonm@mail.nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.846. Awards are made under authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and administered under NIH grants policies and Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public law 103-227, the pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Return to Volume Index
Return to NIH Guide Main Index